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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,915	01/28/2002	Shaun Jordan	01197.0227	1488

7590 09/23/2003

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/23/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/055,915

Applicant(s)
Jordan et al.

Examiner
Phyllis G. Spivack

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1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) 3-20 and 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 21, and 22 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

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Applicants' Preliminary Amendment, Supplemental Preliminary Amendment and Response filed January 28, 2002, July 11, 2002 and June 18, 2003, respectively, Paper Nos. 5, 6 and 10, are acknowledged. Priority to a provisional application is established. Applicants have elected the compound of claims 20 and 32, as a single disclosed carbostyryl compound, and depression, as a single disclosed disorder.

An Information Disclosure Statement filed December 23, 2002, Paper No. 7, is further acknowledged and has been reviewed.

Upon reconsideration the examination has been extended to include both forms of the formula of claim 1, wherein the carbon-carbon bond between 3- and 4-positions in the carbostyryl skeleton is a single or a double bond. Claims 3-19 and 23-31 are withdrawn from consideration by the Examiner, 37 C FR 1.42(b), as being drawn to non-elected inventions. Claims 1, 2, 20-22 and 32, wherein the compounds of claim 1 are used in methods to treat depression, is the subject matter presently under consideration.

Claim 20 is objected to under 37 C FR 1.75© as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 20 not been further treated on the merits.

Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

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The recitations in claims 21 and 22 beginning with "such as" render the claims indefinite. It is unclear whether or not claim limitations are intended.

Claims 1, 2, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as lacking a clear written description of the invention and of the manner and process of practicing it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the same, and, as not setting forth the best mode contemplated by the inventors to carry out the invention.

The claims are directed to treating the disorder of the central nervous system associated with the 5-HT_{1A} receptor subtype that is depression comprising administering a compound of the formula of instant claim 1. The support provided by the specification is solely directed to the administration of the compound of claim 1 wherein there is no double bond between the 3- and 4-positions in the carbostyryl skeleton. Tables 1 and 2 demonstrate potency (EC₅₀), Intrinsic Agonist Efficacy (E_{MAX}) and Inhibitory Potency (IC₅₀) in a membrane binding assay only comprising the use of PC-14597. One skilled in the art finds no guidance with respect to administration of the compound of the formula of instant claim 1 wherein there is a double bond between the 3- and 4-positions in the carbostyryl skeleton. Claim 1 does not find support in the specification for this second option. There is no showing that Applicants had possession of the claimed invention of administering the compound of the formula of instant claim 1 where there is a double bond between the 3- and 4-positions in the carbostyryl skeleton. The present level of skill in the psychiatry art would reasonably require a more detailed written description directed to the

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means of carrying out the claimed methods for therapeutic treatment of depression comprising administering both compounds of instant claim 1.

No claim is allowed.

Yamada et al., Society for Neuroscience Abstracts, is cited to show further the state of the art with respect to another HT_{1A} receptor agonist compound, OPC-14523, as an antidepressant, which differs from OPC 14597 by a methoxy group.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

September 20, 2003

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**